



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

IO

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/680,228 10/06/00 ELLIS

J 454313-2340.

EXAMINER

HM22/0307

THOMAS J KOWALSKI ESQ
FROMMER LAWRENCE & HAUG LLP
745 FIFTH AVENUE
NEW YORK NY 10151

FOLEY, S

ART UNIT

PAPER NUMBER

1648

4

DATE MAILED:

03/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/680,228

Applicant(s)

ELLIS ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: *Notice to comply*.

DETAILED ACTION

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 9-16, 30-33, 39-46, and 60-64, drawn to an immunogenic composition comprising a PCV-2 immunogen, classified in class 424, subclass 184.1.
- II. Claims 1-4, 12-16, 30-34, 42-46, 60-64, drawn to a polypeptide comprising an epitope of a PCV-2 antigen, classified in class 424, subclass 184.1.
- III. Claim 1-3, 5, 12-16, 30-33, 35, 42-46, 60-64, drawn to an immunogenic composition comprising an antibody elicited by a PCV-2 immunogen, classified in class 424, subclass 139.1.
- IV. Claims 1-3, 6, 12-16, 30-33, 36, 42-46, 60-64, drawn to an immunogenic composition comprising an antibody elicited by an epitope of a PCV-2 immunogen, classified in class 424, subclass 139.1.

Art Unit: 1648

- V. Claims 1-3, 7, 9-11, 17-29, 31-33, 37, 39-41, 43-64, drawn to an immunogenic composition comprising a vector expressing a PCV-2 immunogen, classified in class 435, subclass 320.1.
- VI. Claim 1-3, 8-11, 13-29, 31-33, 38-41, 43-64, drawn to an immunogenic composition comprising a vector expressing an epitope of a PCV-2 immunogen, classified in class 435, subclass 320.1.
- VII. Claims 1-3, 12-16, 30-33, 42-46, 60-64, drawn to an immunogenic composition comprising a PCV-1 immunogen that binds to an antibody elicited by a PCV-2 immunogen or epitope, classified in class 424, subclass 136.1.
- VIII. Claims 1-3, 12-16, 30-33, 42-46, 60-64, drawn to immunogenic composition comprising a polypeptide comprising an epitope of a PCV-1 immunogen that also binds to an antibody that elicits a PCV-2 immunogen or epitope, classified in class 424, subclass 184.1.
- IX. Claims 1-3, 12-16, 30-33, 42-46, 60-64, drawn to immunogenic composition comprising an antibody elicited by a PCV-1 immunogen that binds with a PCV-1 immunogen/epitope and a PCV-2 immunogen/epitope, classified in class 424, subclass 130.1.
- X. Claims 1-3, 12-16, 30-33, 42-46, 60-64, drawn to immunogenic composition comprising an antibody elicited by an epitope of a PCV-1 immunogen that binds to a PCV-1 immunogen/epitope and an epitope of a PCV-1 immunogen that binds with a PCV-1 immunogen/epitope and a PCV-2 immunogen/epitope, classified in class 424, subclass 159.1.

Art Unit: 1648

- XI. Claims 1-3, 9-11, 13-29, 31-33, 38-41, 43-64, drawn to immunogenic composition comprising a vector that expresses a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen/epitope, classified in class 435, subclass 320.1.
- XII. Claims 1-3, 9-11, 13-29, 31-33, 38-41, 43-64, drawn to immunogenic composition comprising a vector expressing an epitope of a PCV-1 immunogen that also binds to an antibody elicited by a PCV-2 immunogen/epitope, classified in class 424, subclass 130.1
- XIII. Claims 65 and 66, drawn to a method of making an immunogenic composition, classified in class 435, subclass 69.1, 71.1, or 480.
- XIV. Claims 67, 68, 70, 72, 73, 76-81, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1.
- XV. Claims 69, 71, 74, and 75, drawn to a vector comprising a nucleic acid, classified in class 424, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP §608.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products in Groups I-XII, XIV, and XV constitute apparently different inventions for the following reasons: the polynucleotides, polypeptides, and antibodies, are chemically distinct products unrelated in sequence and are separately classified having separate fields of search. Other than the fact that the polypeptides and the polynucleotides are derived from the same virus, the polynucleotides have no relation to the polypeptides and the antibodies.

Art Unit: 1648

The functional existence of either DNA or protein is not dependent on the existence of the other. The products of each group can be synthesized by chemical means. An antibody is encoded by an entirely different DNA than that of a protein and the primary sequence of the antibody bears no relationship to the protein sequence. It would place undue burden on the examiner to examine several different inventions in one application.

Inventions I-XII, XIV, XV and XIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the independent products in each Group could be synthesized by chemical methods, isolated from cell culture, or recombinant technique and then combined with a pharmaceutical carrier. These methods can be use to make a variety of different products, for example, the products in Groups I-XII, XIV, and XV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

Application/Control Number: 09/680,228

Page 6

Art Unit: 1648

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
March 6, 2001

Mary Mosher
**MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800**
1600